



Billing Code 4165-15

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**

**Information Collection Request Title: Zika Virus Pilot Project, OMB No. 0906-XXXX –**

**New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Zika Virus Pilot Project, OMB No. 0906-XXXX –  
New

*Abstract:* HRSA is requesting the Organ Procurement and Transplantation Network (OPTN) perform a federally sponsored data collection as part of a pilot project to monitor the testing of deceased potential donors possibly exposed to the Zika virus (ZIKV). The Zika Pilot Project will have a 12-month performance period enabling OPTN to develop a plan to collect data on ways for organ procurement organizations (OPOs) to deploy ZIKV donor screening tests of blood products. The testing is available under an investigational new drug application for use on a voluntary basis in the evaluation of deceased persons as potential solid organ donors. OPTN will conduct an analysis of the data collected under this project to determine the potential effect of making available screening tests for ZIKV, when appropriate, to improve transplant safety. OPTN will convene a group of stakeholders to provide guidance and monitor progress on the ZIKV pilot project.

*Need and Proposed Use of the Information:* ZIKV is prevalent in several areas of the United States. Currently, there is not a ZIKV screening procedure for OPOs to implement during the organ allocation process. HRSA requested OPTN to conduct a pilot project to monitor the testing of deceased donors potentially exposed to ZIKV. The goals of the pilot project are to:

- Collaborate with experts to define necessary data elements to understand the impact of ZIKV testing in deceased organ donors;
- Deploy a data collection tool to a limited number of OPOs that agree to participate in the pilot project; and
- Assess the ability of OPTN to respond to a public health situation by collecting data from impacted members of the transplant community to assess the national experience.

*Likely Respondents:* Organ Procurement Organizations

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
ZIKV Data Collection Tool	20	167	3340	.508	1696.7
Total	20		3340		1696.7

\*Total number of responses determined by applying the percentage of OPOs participating to the total number of deceased donors in 2016. Based on OPTN Data as of 11/09/2017.

\*\*Donors screened for ZIKV will be based on OPO specific screening criteria.

HRSA specifically requests comments on: (1) the necessity and utility of the proposed

information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Amy McNulty,**

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*Division of the Executive Secretariat.*

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